K010591

MAR 1 5 2001

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. Submitter's name, address, telephone number, initial importer, contact person

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjukuku Monolis Nishi-Shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration Number : Address, Phone and Fax Of R & D Department Endoscope Division	810047 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-5613

2. Initial Importer

Name : Address :	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL 516-844-5688 FAX 516-844-5416

3. Name of Contact Person

Name :	Tsuyoshi Yanai Manager Regulatory Affairs Quality Assurance Department Endoscope Division
Address, Phone and Fax :	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 TEL 81-426-42-2891 FAX 81-426-46-5613

SK11

B. Device Name, Common Name

1. Common/Usual Name

Diagnostic Ultrasound System with Accessories

2. Device Name

Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

3.Classification Name

	FR Number	Product Code	Class
Bronchoscope and accessories	874.4680	KIT	II
Endoscope and accessories	876.1500	KOG	II
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN	II
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO	II
Diagnostic Ultrasound Transducer	892.1570	ITX	II

C. Identification of the predicate or legally marketed device

The following devices information demonstrates that this device is substantially equivalent to a legally marketed ,predicate medical device.

1. Ultrasound System

Device Name	#K
SonoSite™ Hand-Carried Ultrasound System	K003399
SonoSite SonoHerat™ Hand-Carried Echocardiography System	K994096
Advanced Technology Laboratories(ALT) HDI 5000 Ultrasound System	K961459

2. Ultrasonic Gastrovideoscope

Device Name	#K
Olympus GF Type UM30P Ultrasonic Gastrofiberscope	K963023
Olympus GF Type UM130 Ultrasonic Gastrovideoscope	K971660
Olympus UM-2R/UM-3R Ultrasonic Probes	K982323
Olympus BF Type 240 Bronchovideoscopes	K963033
Olympus GIF-1T140 Video Gastroscope	K954451
Pentax FG-36UX, Ultrasound Upper GI Fiberscope	K961974

D. Device Description

1. Summary

The EU-C60 is a general purpose, compact, software-controlled, diagnostic ultrasound system. The EU-C60 has compatibility with SonoSite transducers (such as abdominal or intracavital transducers) and Olympus Ultrasound videoscope. Its function is to acquire ultrasound data and display it on a monitor in several modes.
(2D, Color Power Doppler, PowerMap™ Directional Color Power Doppler, or in a combination of modes.)
The EU-C60 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes.
The GF-UC160P-OL5/GF-UCT160-OL5 give the operator the ability to perform Endocopic Ultrasound(EUS) guided fine needle aspiration(FNA).

2. Design

The EU-C60 is designed to comply with the standards listed below.

IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-2-18
CISPR11

3. Materials

The material of Balloon3 is a new patient-contacting material. The biocompatibility test reports of the new material show that the new material is safe for its intended use.

E. Intended Use:

The intended uses of the EU-C60, as defined by FDA guidance documents, are:

Fetal - OB/GYN	Musculo-skeletal (conventional)
Laparoscopic	Musculo-skeletal (superficial)
Intraoperative (abdominal organs and vascular)	Neonatal Cephalic
Abdominal	Pediatric
Small Organ (breast, thyroid, testicle)	Cardiac (adult and pediatric)
Trans-vaginal	Trans-esophageal (non-cardiac)
Trans-rectal	Peripheral Vessel
Other 1) Gastrointestinal tract and the surrounding Organs 2) The airways and tracheobronchial tree	

F. Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis.

Technological Characteristics of this device is identical to the predicated devicesIdentified in item 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

Olympus America, Inc.
C/O Mark Job, 510(k) Program Manager
TUV Product Service
1775 Old Highway 8 N.W.
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K010591
Trade Name: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center
Regulatory Class: II/21 CFR 892.1550/CFR 876.1500
Product Code: 90 IYN/78 KOG
Dated: February 27, 2001
Received: February 28, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center, as described in your premarket notification:

Transducer Model Numbers:

ICT/7-4 7.0-4.0 MHz Intracavitary Transducer
L38/10-5 10.0-5.0 MHz Linear Array
C60/5-2 5.0-2.0 MHz Curved Array
C15/4-2 4.0-2.0 MHz Curved Array
GF Type UC160P-OL5
GF Type UCT160-OL5

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N				B+M	Note 1
	Abdominal	N	N				B+M	Note 1
	Intra-operative (Abdominal organs and vascular)	N	N				B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	N	N				B+M	Note 1
	Pediatric	N	N				B+M	Note 1
	Small Organ (breast, thyroid, testicles.)	N	N				B+M	Note 1
	Neonatal Cephalic	N	N				B+M	Note 1
	Adult Cephalic							
	Trans-rectal	N	N				B+M	Note 1
	Trans-vaginal	N	N				B+M	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N				B+M	Note 1
	Musculo-skel. (Convent.)	N	N				B+M	Note 1
	Musculo-skel. (Superfic.)	N	N				B+M	Note 1
	Other (spec.) (Note2)	N	N				B+M	Note 1
Cardiac	Cardiac Adult	N	N				B+M	Note 1
	Cardiac Pediatric	N	N				B+M	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N				B+M	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Note 2:

(1) the gastrointestinal tract and the surrounding organs.

(2) the airways and tracheobronchial tree.

Prescription Use (Per 21 CFR 801.109) David A. Lyman

(Division Sign-Off)
Division of Reproductive, **Abdominal, ENT,** and Radiological Devices

510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: ICT/7-4 7.0-4.0 MHz Intracavitary Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note 3
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P				B+M	Note 3
	Trans-vaginal	P	P				B+M	Note 3
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: L38/10-5 10.0-5.0 MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note 3
	Abdominal	P	P				B+M	Note 3
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 3
	Intra-operative (Neuro.)							
	Laparoscopic	P	P				B+M	Note 3
	Pediatric	P	P				B+M	Note 3
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note 3
	Neonatal Cephalic	P	P				B+M	Note 3
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note 3
	Musculo-skel. (Superfic.)	P	P				B+M	Note 3
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P				B+M	Note 3
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel.	P	P				B+M	Note 3
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, **Abdominal, ENT,** and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: C60/5-2 5.0-2.0 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note 3
	Abdominal	P	P				B+M	Note 3
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 3
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note 3
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note 3
	Cardiac Pediatric	P	P				B+M	Note 3
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel .							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: C15/4-2 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note3
	Abdominal	P	P				B+M	Note3
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note3
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note3
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note3
	Neonatal Cephalic	P	P				B+M	Note3
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note3
	Musculo-skel. (Superfic.)							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note3
	Cardiac Pediatric	P	P				B+M	Note3
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P				B+M	Note3
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: Olympus GF TYPE UC160P-OL5
EUS EXERA Ultrasonic Gastrovideoscope

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N				B+M	Note 1
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 2)	N	N				B+M	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Note 2:

(1) the gastrointestinal tract and the surrounding organs.

(2) the airways and tracheobronchial tree.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: Olympus GF TYPE UCT160-OL5
EUS EXERA Ultrasonic Gastrovideoscope

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N				B+M	Note 1
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 2)	N	N				B+M	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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